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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,676	04/08/2002	Sam Fong Yau Li	2577-118	7819
6449	7590	03/23/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			LUCAS, ZACHARIAH	
		ART UNIT	PAPER NUMBER	1648

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,676	LI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 February 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 73-100 is/are pending in the application.
 4a) Of the above claim(s) 92 and 93 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 73-91 and 94-100 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-8-05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In the prior action, the Final action mailed on September 9, 2004, claims 73-102 were pending. Of these claims, claims 73-91, and 94-102 were rejected, and claims 92 and 93 were withdrawn as to non-elected inventions. The claims were amended in a pair of After-Final amendment filed in December 2004. These amendments were entered, and resulted in the withdrawal of certain rejections as indicated in the Advisory action mailed on January 26 (and again on February 1), 2005.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 8, 2005 has been entered.
3. Claims 73-100 are pending, with claims 92 and 93 withdrawn, and claim 73-91, and 94-100 under consideration. The claims are under consideration to the extent that they read on the elected inventions (immunodiagnostic tests comprising immobilization of a bacterial antigen on a piezoelectric crystal, wherein the antigen or antibody is immobilized by adsorption onto a metal modified crystal), and inventions generic thereto. See, the Restriction Requirement of September 24, 2003, and the Response thereto of November 24, 2003.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on February 8, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.
5. It is noted that an English Language translation of the cited reference has been provided. The reference has therefore been considered to the extent of the English language translation. The reference is considered redundant to the teachings of either of Bastiaans or Larue.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. **(Prior Rejection- Maintained)** Claims 73-91 and 94-102 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claims 101 and 102 have been cancelled. The rejection was withdrawn from claim 82 for the reasons indicated in the Advisory action. The Applicant maintains the traversal of the rejection of the claims by asserting 1) that claim 82 recites three alternative embodiments, each of which is directed to a different application of the metal electrode, and 2) that the recitation in claim 82 does not demonstrate that the other claims do not include a metal electrode.

With respect to argument 1), it is noted that only one of the alternative embodiments of claim 82 is presently under consideration. This is because the various invention recited by this

claim were subject to restriction in the Restriction Requirement, and no generic claim has been found allowable. Thus, this argument is considered moot.

With respect to argument 2, the Applicant argues that the application teaches that the metal electrode is “necessary for inducing resonant frequencies in the Pz devices of the invention,” and that because the claims read on methods requiring the measurement of such resonant frequencies, the presence of the metal electrode is implicitly required. This argument is not found persuasive. While those in the art would have known that a metal electrode is required, the claims do not recite this feature. Rather, each instance in the application where a combination of the crystal and the electrodes is referred to, the application identifies it as a Pz crystal device, which the application defines as consisting of a crystal and two metal electrodes. See e.g., page 4, and page 10. Because the claims merely refer to the crystal, and only refer to the metal electrodes in the dependent claims, it is not so clear that the claims require the presence of the electrodes in each embodiment of the claimed invention. The rejection is therefore maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. (**Prior Rejection- Maintained**) Claims 73, 74, 76, 78-81, 83, 84, 90, 91, 95, 97, and 99-100 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans

et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Thorns (U.S. Patent 5,510,241). U.S. Patent 5,306,644 was cited in the Advisory action as additional evidence that it would have been obvious to those in the art to use the device suggested by the other references in immunological assays in veterinary applications. For the sake of clarity, the recitation of the rejection is hereby restated to be further in view of the teachings of the '644 patent.

10. The Applicant traverses this rejection on the basis of the newly added limitation to claim 73, requiring that the Pz crystal was previously used to test a different biological specimen to the one being tested. The Applicant argues that the '644 patent, newly cited in the Advisory action, only teaches the reuse of a Pz crystal testing device with respect to repeated applications to the same sample. This argument is not found persuasive. First, it is noted that the '644 patent was cited only to support the proposition that it would have been obvious to those in the art to use the device suggested by the other references as previously applied in veterinary applications.

However, as is clear from the prior actions, the rejection is not based solely on the teachings of this reference. In such cases (i.e. where the rejection is based on combinations of references), one cannot show nonobviousness by attacking references individually. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Rather, the cumulative teachings of the cited references must be considered.

In the present case, it was previously described that each of the Bastiaans and Larue references teach the general re-usability of the Pz crystal devices. See e.g., pages 4-5 of the Final Rejection mailed in September 2004. In particular, the Bastiaans reference states in column 6 that "because the antigen or antibody is chemically bonded to the sensor surface, the

corresponding antigen or antibody can be removed after a test procedure has been completed such that the sensor can be reused.” From this, it would have been clear to those in the art that the later reuse would include, if not be more likely to be, a reuse in an assay against a new sample. In view of this, the Applicant’s arguments in traversal are not found persuasive, and the rejection is maintained.

11. **(Prior Rejection- Maintained)** Claims 73-76, 78-81, 83, 84, 90, 91, 95-97, 99 and 100 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Bastiaans et al., (U.S. Patent 4,735,906, of record in the April 2002 IDS), in view of Larue (U.S. Patent 5,705,399) and Rajashekara et al. (WO 98/03656). The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claims.

12. **(Prior Rejection- Maintained)** Claims 77, and 85-89 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara, as these references were applied against the previous versions of the above claims, and of Willner et al. (WO 98/40739, Willner I- of record in the April 2002 IDS). The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claims.

13. **(Prior Rejection- Maintained)** Claim 82 was rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara

as applied to the previous pending versions of the above claims, and further in view of Willner et al. (WO 97/04314, Willner II- of record in the April 2002 IDS). The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claim.

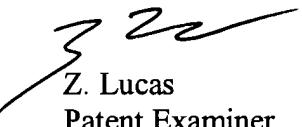
14. **(Prior Rejection- Maintained)** Claims 94 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bastiaans in view of Larue and further in view of either Thorns or Rajashekara as applied to the previous pending versions of the above claims, and further in view of Masten et al., J Bacteriol 175: 5359-65 and in view of Protein Accession CAA78777. The Applicant traverses the rejection for the same reasons as described above. For the reasons above, the traversal is not found persuasive and the rejection is maintained over the new claim.

Conclusion

15. No claims are allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES C. HOUSEL 3/2/05
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